

## REMARKS

In addition to reconsideration of the remarks filed in the Amendment, mailed May 30, 2008, Applicants respectfully request the Examiner to enter the Amendment, mailed May 30, 2008, and to consider the following additional remarks.

Claims 1-35 and 66 are currently in the application. In the Amendment, filed May 30, 2008, claims 1, 35, and 66 were amended. The amendments to claims 1, 35, and 66 were made without prejudice to pursuit of the previous claims in an appropriate continuation application.

As noted in the Amendment, filed May 30, 2008, support for the amendments to claims 1, 35, and 66 can be found throughout the specification and claims as originally filed. No new matter has been added by the amendments to the claims. Additional support for the amendments to claims 1, 35, and 66 can be found in the language of original claims 1, 35, and 66, respectively, and in the specification, e.g., from page 16, line 1, to page 18, line 3; from page 28, line 33, to page 30, line 8; and in the Examples, Figures, and Abstract.

In the Advisory Action, the Patent Office additionally alleges:

The request for reconsideration has been considered but does NOT place the application in condition for allowance because: The newly added language raises new issues that would require further consideration and/or search. The newly added languages “subsequently contacting intact cells”, “subsequently drying” in claims 1, and 35 and “single solution” in claim 35 raise the issue of new matter. Without entering the newly added languages, the rejections set forth in the Office action mailed 12/17/07 are maintained.. [Pp. 1-2.]

Applicants respectfully traverse the remarks of the Patent Office and request entry of the Amendment, filed May 30, 2008, as well as the present Supplemental Amendment and Response to Advisory Action.

**I. “Subsequently”**

With respect to the use of “subsequently contacting intact cells” and “subsequently drying,” Applicants submit that this language is amply supported by the specification and the claims as originally filed.

First, claim 1 and claim 35 are method claims reciting a series of steps, which would imply to one of ordinary skilled in the art, who is familiar with laboratory protocols, that the steps are sequential, similar to a lab protocol or recipe. In particular, the specification states:

The present method provides a quick, simplified, cost effective method for storing, and subsequently isolating, nucleic acids using a wide range of commercially available solid phase media, which until now have been considered inappropriate for storage....[P. 11, ll. 9-12; emphasis added.]

Second, the language of the Examples with respect to the protocol clearly indicates the sequential order of the method steps of claims 1 and 35. The Examiner’s attention is directed to the initial paragraph, particularly to the following:

....25-50 µl FTA® solution (Whatman) were applied to each column after Nucleated Cell Capture and Red Cell Lysis Step. Then columns were left at room temperature for drying, storage and subsequent DNA extraction. [P. 32, ll. 5-7; all emphasis added.]

The Examiner’s attention is also directed to the “Study design for Examples 1-4” (p. 32, ll. 14-32), the “Study design” for Example 5 (p. 35, ll. 18-29), the “Study design” for Example 6 (p. 37, ll. 6-18), the “Study design” for Example 7 (p. 37, l. 34, to p. 38, l. 17), the “Study design” for Example 8 (p. 39, ll. 8-20), and the “Study design” for Example 9 (p. 30, ll. 1-17) with respect to filters/media of various types. In each instance, the Study Design fully describes the ordered steps of claims 1 and 35 in the order described in those claims. Similar support can be found in the Abstract as originally filed in PCT/US2003/031483 (filed October 3, 2003), of which the present application is a national phase application.

Thus, the use of “subsequently” with respect to contacting the intact cells and, later, drying the medium does not add new matter or raise any new issue that would require further consideration or searching.

## **II. “Single Solution”**

With respect to the use of “single solution,” Applicants submit that this language is likewise amply supported by the specification and the claims as originally filed.

First, the “single solution” is supported by the original language of the claims (e.g., original claims 35, and 66), which recite:

...a solution comprising:

- i. a weak base;
- ii. a chelating agent; and
- iii. an anionic surfactant or detergent. [**original** claims 35 and 66]

The “solution” clearly combines all three of these elements. (The Examiner’s attention is also directed to claim 19 [with underlying claim 1].)

Second, the language of the specification clearly indicates that the solution of claim 35 is one, single solution. The Examiner’s attention is directed to the Detailed Description (e.g., from p. 18, l. 5, to p. 20, l. 2), which describes not merely the types of bases, chelating agents, and anionic surfactants/detergents that can be used, but their combination into a single solution.

For example:

The chemical composition of the solution, which...more preferably comprises a weak base, a chelating agent, and an anionic surfactant or detergent, facilitates the lysis of whole cells and the subsequent capture of the released nucleic acids. The chemical composition further aids in their long term storage....[P. 18, ll. 5-9.]

And also:

....The chemical solution can include a weak base, a chelating agent, and the anionic surfactant or detergent, and optionally uric acid and urate salt as discussed in detail in the above-cited United States Patent 5,807,527.... [P. 18, ll. 26-29.]

And also:

In one preferred embodiment, the solution used in this aspect of this invention comprises the following:

- (i) a monovalent weak base (such as "Tris", tris-hydroxymethyl methane, either as the free base or as the carbonate);
- (ii) a chelating agent (such as EDTA, ethylene diamine tetracetic acid); and
- (iii) an anionic detergent (such as SDS, sodium dodecyl sulfate); and optionally
- (iv) uric acid or a urate salt.

An example of one preferred embodiment of the solution is an FTA® solution (Whatman, Inc.) comprising Tris, EDTA, SDS, and uric acid. [P. 19, ll. 1-9.]

In addition, the FTA® solution is also described as an "FTA® cocktail" (p. 20, l. 27), and the disclosure of the aforementioned U.S. Patent 5,807,527 is incorporated by reference, in addition to U.S. Patents 5,756,126 and 5,496,562 (see, e.g., p. 18, l. 20 and from p. 40, l. 33, to p. 41, l. 3).

Moreover, the Examiner's attention is directed to the Examples and directed to the initial paragraph, particularly to the following:

....25-50  $\mu$ l ***FTA® solution (Whatman)*** were applied to each column after Nucleated Cell Capture and Red Cell Lysis Step.... [P. 32, ll. 5-6; all emphasis added.]

The Examiner's attention is also directed to the "Study design for Examples 1-4" (p. 32, ll. 19-21), the "Study design" for Example 5 (p. 35, ll. 22-24), the "Study design" for Example 6 (p. 37, ll. 10-12), the "Study design" for Example 7 (p. 38, ll. 7-11), the "Study design" for Example 8 (p. 39, ll. 12-14), and the "Study design" for Example 9 (p. 30, ll. 8-10) with respect to the use (or absence) of an aliquot of FTA® solution.

**Clearly, the above passages describe a single aliquot of solution comprising various elements – not a series of sequentially added solutions.**

Thus, the use of "single solution" does not add new matter or raise any new issue that would require further consideration or searching.

Applicants respectfully submit that amended claims 1 and 35 do not raise the issue of new matter or require further consideration and/or search, placing these claims in condition for allowance, and request the Examiner's reconsideration accordingly.

## CONCLUSION

It is believed that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants hereby request a three-month extension of time for the Amendment and accompanying materials. If, however, a petition for an additional extension of time is required, then the Examiner is requested to treat this as a conditional petition for an additional extension of time and the Commissioner is hereby authorized to charge our deposit account no. 04-1105 for the appropriate fee. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,



Kathryn A. Piffat, Ph.D., (Reg. No. 34,901)  
EDWARDS ANGELL PALMER & DODGE, LLP  
P.O. Box 55874  
Boston, Massachusetts 02205  
Telephone: 617-239-0100  
Facsimile: 617-227-4420

Date: October 2, 2008

Customer No. 21874